

EXHIBIT F

Page 1

1 UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY
3 MDL No. 2875

4
5 IN RE: VALSARTAN, PRODUCTS)
6 LIABILITY LITIGATION)
7)
8 TESTIMONY OF:)
9 Stephen Hecht, Ph.D.)
10)

11 August 17, 2021

12 9:00 a.m.

13
14 TRANSCRIPT of the stenographic notes of the video
15 recorded proceedings in the above-entitled matter, as
16 taken by and before Sara K. Killian, a Registered
17 Professional Reporter, Certified Court Reporter and Notary
18 Public, remotely via Zoom videoconferencing.

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1 association between lung cancer and NDMA in
2 valsartan, correct?

3 A. That's correct. But I wonder if
4 these were all nonsmokers. I don't know if that's
5 the case.

6 Q. No statistically significant
7 association between pancreatic cancer and NDMA in
8 valsartan, correct?

9 A. Correct. Well, malignant melanoma.

10 Q. No statistically significant
11 association between prostate cancer and NDMA in
12 valsartan, correct?

13 A. Correct.

14 Q. No statistically significant
15 association between uterine cancer and NDMA in
16 valsartan?

17 A. Right.

18 Q. Do you agree that the metabolism of
19 NDMA and NDEA is the only mechanism by which these
20 substances could possibly cause a mutation?

21 A. Yes.

22 Q. So NDMA and NDEA could circulate in
23 the body and unless and until they become
24 metabolized, they'll just be excreted without
25 causing harm, right?

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1 A. Say that again, please.

2 Q. Absent -- what I was saying was until
3 NDMA and NDEA become metabolized, they would
4 simply be excreted from the body without causing
5 harm?

6 A. That's true, but, in fact, you see
7 very little excretion of unchanged NDMA in the
8 urine. When it's taken orally, it's metabolized
9 very effectively by the liver and other tissues.

10 Q. Does most of the metabolism of the
11 NDMA occur in the liver?

12 A. As far as we know, yes.

13 Q. And at this point in time, would you
14 say that the scientific community has good data on
15 the metabolism of NDMA and NDEA in the human body?

16 A. Yes.

17 Q. Do you agree then that the primary
18 metabolism of NDMA and NDEA takes place through
19 the cytochrome P450 enzyme?

20 A. Yes.

21 Q. And that's in the liver. That's
22 where that enzyme is primarily located, right?

23 A. No. They're in other tissues also.

24 Q. It's not in every organ system of the
25 body, is it?

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1 A. Just about.

2 Q. Just the enzyme?

3 A. Yes. There are different forms in
4 different tissues. Not just in the liver. The
5 lung, kidney, small intestine, esophagus, oral
6 cavity. They all have P450 enzymes. The liver,
7 of course, is the main metabolizing organ in the
8 body and has a higher P450 content than other
9 tissues, but all tissues have P450s. Different
10 ones. There are whole books written on it.

11 Q. Okay. I'll take your word for it.

12 Does the scientific community at this
13 point in time have a great deal of valid reliable
14 data about the type of DNA damage caused by NDMA
15 and NDEA?

16 A. Yes.

17 Q. Have you ever stated that there are
18 ways to look at a DNA adduct formation and how
19 much damage comes from nitrosamine exposure but
20 right now, in 2021, we don't have that type of
21 data?

22 A. I'm not sure I understand your
23 question.

24 Q. My question is simply have you ever
25 made the statement that "We do not have the data

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1 the NDMA is exceeded?

2 A. That data is in the literature.

3 There's plenty of data on that --

4 Q. Did you make any --

5 A. -- from the pharmacokinetic studies
6 and even from the early studies of Magee and Swan
7 that when the metabolic capacity of the liver is
8 exceeded in an oral dose, then kidney tumors start
9 to appear and there's plenty of data on that. Not
10 only tumors, but DNA adduct studies and metabolism
11 studies. There's a lot of data regarding the
12 first pass clearance of NDMA given orally, a lot
13 of data. We understand that really very well.

14 Q. So it follows, Doctor, that you would
15 understand and agree with the point that NDMA will
16 not escape the liver unless the level is at such a
17 point that it exceeds the liver's capacity to
18 metabolize it, correct?

19 A. That's what the -- that's what all
20 the data indicates. That's correct.

21 Q. I'm also correct that sitting here
22 today, you are offering no opinion as to what that
23 level of NDMA is, correct?

24 A. In humans?

25 Q. Sir, yes.

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1 A C K N O W L E D G M E N T

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3 I, STEPHEN HECHT, Ph.D., hereby certify that I
4 have read the transcript of my testimony taken under oath
5 in my examination of August 17, 2021; that the transcript
6 is a true, complete and correct record of what was asked,
7 answered and said during this deposition, and that the
8 answers on the record as given by me are true and
9 correct.

10 _____

11 STEPHEN HECHT, Ph.D.

12

13 Signed and subscribed to
14 before me, this day of
15 2021.

16 _____

17 Notary Public

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